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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO.       | CONFIRMATION NO. |
|---|-------------|-----------------------|---------------------------|------------------|
| 09/661,153  | 09/13/2000  | Matthew A. Howard III | UIOWA-8PAD1               | 7887             |
| 34610   | 7590        | 12/22/2003            | EXAMINER                  |                  |
| FLESHNER & KIM, LLP<br>P.O. BOX 221200<br>CHANTILLY, VA 20153 |             |                       | WILLIAMS, CATHERINE SERKE |                  |
|   |             |                       | ART UNIT                  | PAPER NUMBER     |
|   |             |                       | 3763                      |                  |
|   |             |                       | DATE MAILED: 12/22/2003   |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/661,153

Applicant(s)

HOWARD III, MATTHEW A.

Examiner

Catherine S. Williams

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 8-10, 12-15, 40-44, 52, 53 and 56-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8, 12, 13, 41, 52, 53, 56, 62-64, 68-71 and 73 is/are rejected.
- 7) ☒ Claim(s) 9, 10, 14, 15, 40, 42-44, 57-61, 65-67, 72 and 74-79 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 71 and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenberg (US Pat# 5,100,395).

Rosenberg discloses a plurality of catheters (4,6,8) disposed non-coaxially side-by-side with respect to one another (see figure 1). The device also includes a pump (see 2:52), a plurality of drug delivery ports along the length of the catheters (12), and a macrocatheter (2 and 9). Since the catheters of the prior art are essentially open tubular conduits with lumens and distal ports, the catheters are considered to be configured to receive a drug and infuse the drug into the hypothalamus of a patient.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8,12,52-53,56,63-64 and 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiResta et al (5,484,399). DiResta discloses (i) a plurality of catheters

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disposed non-coaxially side by side (12) with a plurality of ports disposed along the length of each catheter (16), (ii) a manifold (14), (iii) a supply line (see figure 1A) and (iv) a pump (20). The pump is configured to operate at a variable rate (see 5:38-40) which can be controlled percutaneously through the use of a sensor inserted within the tissues (see 6:4-8). DiResta discloses that the pump chosen can be the suction side of a suction/delivery pump. See 5:42-44. Additionally, an objective of the device is to reduce interstitial fluid pressure (IFP) to thereby enhance the penetration of drugs into a tumor (i.e. brain tumor). See 3:4-5. However, DiResta fails to disclose a pump configured to controllably supply a drug to the catheters.

At the time of the invention, it would have been obvious to rearrange the configuration of the suction/delivery pump of DiResta to attach the delivery side of the pump to the manifold and catheter of the device. The motivation for this rearrangement is found within the reference itself. As taught by DiResta, an objective of the device is to enhance the penetration of drugs by suctioning out IF. Once suctioning is complete, it would be obvious to use the device, while already in place, to switch the pump to infuse drugs to the tumor area in order to reduce the number of invasive procedures on a patient and thereby enhance the safety of the patient.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over DiResta. DiResta meets the claim limitations as described above but fails to include controlling the pump by a radio control unit. However, it is well known in the art to use radio control signals and devices to link subcutaneous parts of a device to controllers/pumps of the device that must be located outside a patient's body. One reason for using a radio control device is to provide a wireless

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communication; thereby, reducing the number of openings or invasive devices in a patient's body.

At the time of the invention, it would have been obvious to connect the sensor to the pump of DiResta by radio control. The motivation would have been in order to reduce the number of invasive device entering into the patient's body; thereby, reducing the chance of infection to the patient.

Claims 41 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiResta. DiResta meets the claim limitations as described above but fails to include a weight controlling drug.

At the time of the invention, it would have been obvious to incorporate any drug including a weight-controlling drug into the invention as a matter of obvious design choice. Applicant's disclosure fails to provide any critically for how the type of drug infused would affect the design of the device. Additionally, the device would perform equally as well infusing a weight-controlling drug into the patient. Therefore, the motivation for incorporating a drug for controlling weight would have been in order to expand the usability of the device into other therapeutic uses.

***Allowable Subject Matter***

Claims 9-10, 14-15, 40, 42-44, 57-61, 65-67, 72 and 74-79 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments filed 9/30/03 have been fully considered. Regarding claims 71 and 73, they are not persuasive.

Applicant argues that the catheters of Rosenberg are not protrusibly located (i.e. cannot be extended or retracted) within the macrocatheter of Rosenberg. The examiner notes that while applicant can be his or her own lexicographer it is applicant's responsibility to disclose within the specification the meaning of words that define the meets and bounds of a claim. Applicant has not provided his own definition of "protrusibly" within the specification; therefore, one skilled in the art can look to common definitions and usages of the word to understand the claim. However, "protrusibly" is not currently a word recognized by the on-line version of Merriam Webster's Dictionary, <http://www.merriamwebster.com/cgi-bin/dictionary>. Therefore, the examiner relied on a listing of protrusible which was a variation of protrude. The closest definition to "extended or retracted" was "to jut out from the surrounding surface". See <http://www.merriamwebster.com/cgi-bin/dictionary>; protrude under *intransitive senses*. This definition does not suggest an action of extending or retracting. Therefore, if one applies the common definition of protrude or "to jut out from the surrounding surface", the prior art reference of Rosenberg clearly shows the catheters jutting out from the surrounding macrocatheter.

Applicant also argues that Rosenberg does not disclose a macrocatheter. The rejection above has been altered to obviate those arguments by including the entire length of catheter 2 with element 9 to define the macrocatheter.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine S. Williams *CSW*.  
December 13, 2003

*Brian L. Casler*  
BRIAN L. CASLER  
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